510(k) Summary

OCT 3 0 2006

This summary of the 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

510(k) Number K061234

Sponsor:

GlucoPlus Inc.
2323 Halpern
Ville St-Laurent, Quebec
Canada H4S 1S3

Contact Information:

Jeffrey Fleishman
Official Correspondent
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Date Prepared: April 25, 2006

Proprietary Name: GlucoPlus™ Blood Glucose Monitoring System

Common Name: Blood Glucose Monitoring System

Classification Name:	**Product Code**	**Device Class**	**Regulatory Numbers**
Test, Blood Glucose System Over the Counter	NBW	2	21 CFR 862.1345
Glucose Oxidase	CGA	2	
Single (Specified) analyte controls (assayed and unassayed) Quality Control Material	JJX	1	21 CFR 862.1345

Panel: (75) Chemistry

Predicate Device: GLUCOMETER ELITE Blood Glucose meter

Manufacturer: Bayer Corporation

510(k) Number k964630

Device Description: GlucoPlus™ Blood Glucose Monitoring System is comprised of an electrchemical biosensor glucose reagent test strip, a hand held meter, quality control solutions, a user manual, a check strip, a lancet, lancets and a logbook for recording test results. When the user inserts a test strip , the meter turns on. The user acquires a blood sample by touching the aperture of the test strip to the finger tip blood drop to fill the chamber on the strip. The meter sounds a beep to let the user know that the sample chamber is full and the reaction has begun. When the test is complete, the meter displays the glucose reading on its LCD.

Similarities with Predicate Device:

Feature / Claim	Detail
Intended Use	The Glucoplus™ Blood Glucose Test System is comprised of Control Solutions and Test Strip biosensors for use only with the Glucoplus™ Blood Glucose Meter. It is for quantitative measurement of the concentration of glucose in capillary whole blood taken from the fingerstick by people with diabetes at home and/or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.
Test Principle	GlucoPlus™ Blood Glucose Monitoring System utilizes a test strip that contains the enzyme glucose oxidase and a glucose meter. After the blood is drawn into the test strip, glucose in the sample reacts with potassium ferricyanide in the test strip producing potassium ferrocyanide. Potassium ferrocyanide is produced in proportion to the glucose concentration in the blood sample. Oxidation of the potassium ferrocyanide produces an electrical current which is then converted by the meter to display the glucose concentration of the blood sample.
Warnings and Precautions	For in vitro diagnostic use.
Sample Types	Fresh capillary whole blood samples from a fingerstick.
Hematocrit Range	30 – 55%
Power Source	3 V lithium battery (CR 2032)
Battery Use Life	More than 1000 tests.

Differences with Predicate Device:

Feature	GlucoPlus™	Glucometer Elite™
Blood Sampling Into Strip	Double Sided (Right or Left)	Sip- in Sampling Front end only
Sample Volume	1.5 µL	2.0 µL
Strip Packaging	25 Strips stored in a vial	Single strip in foil package.
Measuring time	Within 15 seconds	Within 30 seconds
Measuring Range	40 – 600 mg/dL	20 – 600 mg / dL
Measuring Unit	Test results are displayed in either mg/dl or mmol/L depending on the meter setting.	mg/dl or mmol/L
Buttons	3 Buttons Center Button: Power Left Button: Setting Functions Right Button: Memory Functions	No Buttons
Setting Functions	Date, Time, Unit of Measure	None
Calibration	Built in Button	Calibration Strip
Data Download	Test Results can download by RS232 or USB interface	N/A
Average Display	Calculate mean results within 1,7,14,21 and 28 days	Total mean results only.
Control Test Mode	N/A	The Control solution test result will not store into memory.
Flashing Strip Symbol	Flashing Strip Symbol will display when meter is powered on.	N/A
Ready to Test Symbol	User can apply blood to strip after the display on LCD appears	The Function Number (F#) and the previous test result begin flashing alternately.

Data Demonstrating Substantial Equivalence:

The results of the consumer and point of care studies demonstrate good correlation (R>0.98) between ~40 - ~550 mg/dl in capillary whole blood specimens. The regression analysis of the data supports the Substantial Equivalency claim with the predicate device.

Consumer Study

Linear regression between GlucoPlus™ and YSI for lay users and technician

Accuracy of lay users compared to YSI using capillary whole blood on 120 specimens at clinical centers	N=120 Y=0.96X-7.90 R=0.985 Sy.x= 12.90 Range=57-481 mg/dL
Accuracy of technician compared to YSI using capillary whole blood on 120 specimens at clinical centers	N=120 Y=0.95X-6.60 R=0.989 Sy.x=10.75 Range=57-481 mg/dL

Point of Care Study

Linear regression between GlucoPlus™ and GLUCOMETER ELITE® for test on department of Home Medical, Internal, and Metabolism

Home Medical	Metabolism	Internal	Total
N=58 Y=1.054X-6.34 R=0.990 Sy.x=11.93 Range=59-341 mg/dL	N=62 Y= 1.031X-6.06 R=0.986 Sy.x=15.87 Range=56-392 mg/dL	N=80 Y=1.046X-4.83 R=0.997 Sy.x=11.98 Range=38-548 mg/dL	N=200 Y= 1.045X-5.81 R= 0.994 Sy.x=13.30 Range=38-548 mg/dL

System accuracy results.

Glucose concentration < 75 mg/dL		
Within 5 mg/dL	Winthin 10 mg/dL	Within 15 mg/dL
14/28 (50%)	25/28 (89.3%)	28/28 (100%)
Glucose concentration □ 75 mg/dL		

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
58/172 (33.7%)	130/172 (75.6%)	160/172 (93%)	170/172 (98.8%)

Conclusion:

The description and data comparing the GlucoPlus™ and GLUCOMETER ELITE® system functions, intended use, hardware and software, laboratory and clinical evaluations supports the substantial equivalency claim to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

GlucoPlus Inc.
c/o Mr. Jeffrey Fleishman
Plasma Services Group, Inc.
315 Parkview Way
Newtown, PA 18940

OCT 3 0 2006

Re: k061234
Trade/Device Name: Glucoplus™ Blood Glucose Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: October 2, 2006
Received: October 4, 2006

Dear Mr. Fleishman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication of Use Statement

510(k) Number (if known): **k061234**

Device Name: Glucoplus™ Blood Glucose Test System

Indications for Use:

The Glucoplus™ Blood Glucose Test System is comprised of Control Solutions and Test Strip biosensors for use only with the Glucoplus™ Blood Glucose Meter. It is for quantitative measurement of the concentration of glucose in capillary whole blood taken from the fingerstick by people with diabetes at home and/or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use X AND / OR Over-the-Counter Use X
(Part 21 CFR §801 Subpart D) (21 CFR §807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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